Antoinette

FYI

D. Wright

ABBOTT

FROM: Don G. Wright, Vice President
Corporate Quality Assurance

INTEROFFICE CORRESPONDENCE

DEPT: 388 **BLDG:** AP6C **EXT:** 7-4575

TO: Mr. T. Hodgson D-392 AP6D
[redacted] D-T01 BBURN
Mr. M.Carroll D-388 AP6C

cc: Mr. D. Durand D-T36 BBURN
Mr. C. Wadley D-316 AP6C

DATE: December 15, 1995

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CONTROLLED COPY # 16
TO BE RETURNED TO D-316

RE: COMPLIANCE ASSURANCE AUDIT OBSERVATIONS
TAP/EPSILON PRESCRIPTION DRUG MARKETING ACT
NOVEMBER 13-17, 1995

Attached are the specific observations resulting from the Compliance Assurance Audit of **TAP - EPSILON** during the period of **November 13-17, 1995.**

The audit was based on the Prescription Drug Marketing Act of 1987 as well as applicable Policies and Procedures.

The audit was qualitatively rated and a "Satisfactory" status assigned to the operation.

TAP should develop an Action Plan which is responsive to the attached observations and, under the signature of the President, forward one (1) copy to me, one (1) copy to Mr. Hodgson, and one (1) copy to Mr. Wadley by January 22, 1995. The Action Plan is to be reviewed by Mr. Hodgson and me as part of our determination of the need for an executive management review of the audit.

TAP is requested to submit six month status reports to Corporate Quality Assurance until all action items are completed. The timing of these reports begins with the issue date of the Action Plan.

Don

Don G. Wright

DGW/cjk
Attachment

TAP00063667

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DEFENDANT'S EXHIBIT
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ABBOTT

INTEROFFICE CORRESPONDENCE

FROM: Quality Assurance Program Manager
Abbott HealthSystems Division

DEPT: 549 **BLDG:** AP34 **EXT:** 8-4005

TO: Mr. D. Wright D-388 AP6C

DATE: December 5, 1995

CC: Mr. M. Carroll D-388 AP6C
Mr. M. Foley D-387 AP6C
Mr. D. McClurg D-549 AP34
Mr. D. Turner D-549 AP34
Mr. S. Wadley D-316 AP6C

TAP00063668

RE: PRESCRIPTION DRUG MARKETING ACT COMPLIANCE ASSURANCE AUDIT-TAP/EPSILON

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Attached are the specific observations resulting from the compliance assurance audit of TAP/Epsilon during the period November 13-17, 1995. The audit team, consisting of David McClurg and Doug Petit (team leader), reviewed records and procedures of the TAP sampling program administered by Epsilon, a third party supplier. The objectives of this audit were to assess TAP compliance to PDMA, to assess Epsilon adherence to contractual agreements established with TAP, to identify any specific sample accountability practices that may expose the Corporation to risks or liabilities for civil penalties imposed under PDMA or state law, specifically those related to practitioner licensing requirements for Nurse Practitioners and Physician Assistants, and finally, to assess the progress made by TAP in addressing observations from the previous compliance audit of October 1992.

TAP currently has a total sales force of approximately 540 individuals, of which there are about 400 sales representatives distributing drug samples. TAP contracts with Epsilon to process and maintain sampling transaction records required by PDMA. Epsilon receives sample disbursement and reimbursement documents from the sales representatives and maintains a perpetual book inventory of samples in each territory. Sample reimbursement is made monthly from the Chicago Distribution Center. TAP sales representatives currently distribute samples of Lupron, Prevacid and MetroGel-Vaginal, the latter under a contract with Curatek Pharmaceuticals.

Sale representatives until recently detailed and sampled Hytrin tablets and capsules under an agreement with PPD. Currently there are no sampling programs using business reply cards (BRC) and there are no samples distributed to practitioners by mail or by common carrier. However, TAP is reportedly in the final stages of an agreement with Medi-Promotions Inc. to provide practitioners with samples of Prevacid through Medi-Scripts®, a third party which provides sample packaging, solicitation using BRC's, and distribution by common carrier.

TAP is to be commended for demonstrating due diligence in successfully addressing each observation from the previous audit, for successfully making the transition from a common carrier sample

distribution system to one using sales representatives, and for accomplishing these activities successfully while expanding the sales force approximately 100% since the previous audit.

Regardless of the preceding accomplishments, the auditors have a number of concerns including findings that TAP has clearly not maximized the PDMA compliance potential available from Epsilon nor has adequate attention been given in the past to assuring that the field sales force fully supports efforts to remain in compliance.

The auditors reviewed 1,545 sample request forms and associated documents from a random selection of 20 sales territories. It is the auditors' opinion that the Joint Venture meets PDMA requirements to distribute drug samples by sales representatives and is rated **satisfactory** because of the following:

1. TAP provided, in a timely manner and with minor exceptions, requested forms, receipts and records, as required by PDMA.
2. Epsilon demonstrated expertise with a sophisticated computer based system of monthly sample reconciliation.
3. Epsilon provides TAP Sales Management with monthly sample reconciliation, sample summary, variance trends, and other sample control reports.
4. TAP has indemnification of $1,000,000 per occurrence against Epsilon performance errors and /or omissions.
5. TAP has procedures in place to meet the reporting requirements of the Act, specifically those requirements relating to thefts and losses.

The auditors found the following areas of concern:

1. Documentation of annual inventories of samples in the possesssion of representatives were not available for all territories audited.
2. TAP could not document that drug samples in the possesssion of certain representatives were stored under proper conditions.
3. Records of unresolved sample variances suggest that TAP field sales managers have not responded in a timely manner to reports showing significant variances over extended periods.

The auditors appreciate the assistance provided by TAP Sales Administration and Quality Assurance and to Epsilon for exception cooperation and assistance during the audit.

David McClurg

Doug Petit

CONFIDENTIAL
CORPORATE COMPLIANCE AUDIT

OBSERVATIONS OF
TAP/EPSILON PDMA COMPLIANCE

TAP00063670

NOVEMBER 13 - 17, 1995

1. Original Sample Signature Cards are missing from the Epsilon records for a number of territories. For example, in territory BXA07, twenty eight cards, spanning the period August 4, 1994 through April 20, 1995, are reportedly fax copies of the original. In 13 cases, where the copy is legible, the document is clearly a copy of the original form intended for Epsilon. Although the cards were accepted by Epsilon and entered into the reconciliation process, there are no procedures allowing fax transmission of Sample Signature Cards to Epsilon nor is there a procedure to preclude duplicate entry of samples if the original cards are subsequently sent to Epsilon.

2. The TAP sales representative sample guide prohibits whiteouts on documents. Several instances were noted where representatives altered documents with whiteout and the documents were subsequently accepted by Epsilon. In one instance, Epsilon reportedly used whiteout on ten Sample Signature Cards and wrote over the serial number because the faxed copy was not legible.

3. Highly questionable signatures were noted on a number of Sample Signature Cards. In some instances, signatures clearly did not match the practitioner name preprinted on the card. In other cases, signatures reportedly signed by the same practitioner were grossly different. Territories with questionable signatures include FXF06 (5463432), EXB09 (4107777) & (3766111), DXD06 (5130459). TAP does not have a procedure to review or verify signatures.

4. Reportedly, all sales representatives are trained in sample accountability as a condition for receiving drug samples. However, there are no procedures addressing this purported requirement in any material provided to the auditors nor are there any procedure requirements to document training. Although records for some representatives contained Sample Accountability Training sign-in sheets, there were no records for many of the twenty sales territories reviewed.

5. PDMA requires the written request for a drug sample contain the professional designation of the practitioner making the request. Even though the professional designation was missing from Sample Signature Cards from many sales territories, these cards had been accepted by the TAP/Epsilon system.

6. PDMA requires, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives and requires drugs to be stored under appropriate conditions. In a review of records of 9 sales territories active for more than twelve months, it was noted that three territories did not have an inventory or storage condition statement in the past 12 months as required

7. The Epsilon procedural manual for processing TAP documents states, "Twice a year the District Manager (D.M.) will also do an audit and sign the inventory statement." This statement contradicts the TAP Sample Accountability Manual which states, "Once a year your district manager will physically verify your inventory figures." Reportedly, neither Epsilon nor TAP has a procedure to assure that the PDMA required inventory is done at least annually.

8. PDMA requires the written request for a drug sample contain the identity of the drugs sample requested. TAP used preprinted Sample Signature Cards listing Hytrin 5 X 21 Tablets and Hytrin 5 X 21 Capsules without listing the strength. Reportedly, the packages contain a combination of 1mg., 2mg., 5 mg. and 10 mg. tablets and capsules, respectively.

9. PDMA limits distribution of drug samples to practitioners licensed to prescribe such drugs. TAP representatives distribute prescription drug samples to Physician Assistants (PA's) and Nurse Practitioners (NP's), and Epsilon has a published procedure for accepting and recording Sample Signature Cards. TAP and Epsilon use a list of states allowing sampling to PA's and NP's which reportedly was provided by PPD and reportedly reviewed by the Abbott legal department. In a review of documents the following were noted:

    a.) The list is not a controlled document and neither TAP nor Epsilon has procedures to verify or maintain the list.

    b.) Although neither Virginia nor Texas is on the TAP list for states allowing sampling, PA's in both states were sampled by TAP representatives.

10. The TAP Sample Accountability manual states "***Theft*** - *If you were a victim of a robbery which involved samples, you must notify the police and attach a police report to an adjustment form.*" Reports of theft were filed by territory DXB01 and AXC06 using the Epsilon Inventory Adjustment forms on 1/17/95 and 7/5/95, respectively, without attaching a police report. Epsilon processed the losses as inventory adjustments and did not call the TAP Sample Coordinator as required in TAP BOP # S-006. Reportedly, the Epsilon Inventory Adjustment forms were completed in error and the thefts never occurred.

11. TAP's SOP No. S-003A defines significant loss as a.) A consistent incidence of loss associated with a specific Sales Representative or carrier, b.) Any loss associated with falsification of records, c.) Any diversion activity, d.) Any loss associated with other suspicious activity, and e.) Any loss of 50 units or more. In reviewing the "TAP Variance

Trend Report," it was noted that eleven (11) territories had variances greater than 50 sample units for three or more months. There is no procedure to determine if these variances are losses reportable to the FDA.

12. TAP SOP # S-011 requires adjustments to inventory records greater than 10 units must be approved by Sales Administration management. Several adjustments for quantities greater than 10 units were observed to have been made without Sales Administration management approval. For example, an adjustment of 80 units of Hytrin was made to the records for territory DXD04 on 9/13/95 without the required approval.

13. The Epsilon Procedure Manual for Tap Pharmaceuticals Documentation is used by Epsilon to train Epsilon personnel and to define TAP document processing. This manual is not a controlled document nor is it reviewed and approved by TAP.

Review TAP SOP and revise it to minimum legal requirement level.

TAP00063672